REMARKS

Summary of the Office Action

Claims 21-40 are pending in the application, and claims 27-30 have been withdrawn from consideration.

Claims 21-22, 24-26, 33, and 36-39 have been rejected under 35 U.S.C. 102(b) as allegedly anticipated by U.S. Patent No. 5,649,959 to Hannam et al. ("*Hannam*").

Claims 21-26, 31-32, and 37-40 have been rejected under 35 U.S.C. 102(b) as allegedly anticipated by U.S. Patent No. 5,545,178 to Kensey et al. ("*Kensey*").

Claims 34-35 have been rejected under 35 U.S.C. 103(a) as allegedly obvious over *Kensey* in view of U.S. Patent No. 6,391,037 to Greenhalgh ("*Greenhalgh*").

Applicant's Response

**A. The 35 U.S.C. 102(b) Rejections**

Applicant submits that all claims rejected under 35 U.S.C. 102(b) are patentable over the *Hannam* and *Kensey* references, because neither *Hannam* nor *Kensey* disclose each and every element of the rejected claims. For example, neither *Hannam* nor *Kelsey* teaches "[a] device for sealing a puncture tract by forming and extruding an autologous plug within the puncture tract", and "a housing having a lumen adapted to mix a volume of blood with a blood congealing agent," as recited in Applicant's independent claim 1.

**1. The Hannam Reference**

*Hannam* discloses an assembly for sealing an opening in the wall of a living vessel that includes a flexible plunger translating within a sheath inserted into the vessel. The flexible plunger first pushes an anchor member into the vessel, and the plunger is successively replaced by a double-lumen syringe, which injects a gelatinous material into the puncture tract while the sheath is being withdrawn form the same tract. The gelatinous material consists of a

bioabsorbable and preferably hemostatic material, for example, a fibrin glue that is cured with the addition of a curing agent.

*Hannam* does not teach that the gelatinous material used for sealing the puncture tract is "autologous," contrary to the recitation of Applicant's claim 1. In particular, *Hannam* does not teach that the patient's blood may be utilized to form an autologous plug. On the contrary, *Hannam* teaches the use of **non-autologous plugs**, such as plugs formed by mixing fibrinogen with thrombin, which are procured from external sources and which are mixed only during injection to avoid the formation of clots in the syringe. *Hannam*, Col. 8, line 32- Col. 9, line 21.

Also contrary to the recitation of claim 1, *Hannam* **does not teach that blood from the patient may be mixed with a congealing agent inside the device**. By comparing, for example, FIGS. 3-8 in *Hannam* with the embodiment illustrated in Applicant's FIG. 3, one skilled in the art will appreciate that *Hannam*'s device is structured to avoid the penetration of the patient's blood into the device, while, on the contrary, Applicant's device is structured to promote the controlled penetration of the patient's blood into the device for mixing with the blood congealing agent. In fact, *Hannam* teaches away from having the patient's blood enter the syringe by stating : "The anchor member **30** functions to ensure that none of the gelatinous material **52** enters the artery and also to ensure that the gelatinous material **52** has an opportunity to cure without substantial amounts of blood or other fluids immediately diluting the fibrin or thrombin materials." *Hannam*, Col. 12, lines 52-46.

For at least the above described reasons, Applicant's independent claims 1, and the claims depending therefrom, are not anticipated by *Hannam*.

**2. The Kensey Reference**

*Kensey* discloses a system and a method for sealing a

percutaneous puncture in living vessel and in the neighboring tissue, by using a trocar to insert an anchoring member into the vessel and also to insert an optional sealing member into the neighboring tissue. The anchoring member and the sealing member are eventually stitched into the tissue.

The sealing member in *Kensey* "basically comprises a strip of a compressible, resorbable, collagen foam … [which] includes a thin web or strip of a non-resorbale, e.g. dacron, reinforcing mesh **46** embedded within it." *Kensey*, Col. 8, lines 25-29.

Therefore, the sealing member in *Kensey* is not an autologous plug, because it is made from **non-autologous materials**, contrary to the recitation of Applicant's independent claim 1. Additionally, the plunger inside the trocar is **not structured to controllably mix the patient's blood with a blood congealing agent**, both because no blood congealing agent is employed in *Kensey's* invention, and also because the function of *Kensey*'s trocar is to operate as a plunger for inserting the anchoring member and the sealing member into the puncture tract. See, e.g., *Kensey*'s FIGS. 1-5.

For at least the above described reasons, Applicant's independent claims 1, and the claims depending therefrom, are not anticipated by *Kensey*.

**B. The 35 U.S.C 103(a) Rejection**

Applicant submits that claims 34 and 35 are not obvious in view of *Kensey* and *Greenhalgh*, because Kensey does not teach Applicant's invention and further because *Greenhalgh* fails to correct the deficiencies of *Kensey*.

The Examiner has stated that "Kensey discloses the invention substantially as claimed" in claim 34-35 except for the use of platinum wire as a blood congealing agent, and has cited *Greenhalgh* for the proposition that platinum wire may be employed as a blood congealing agent.

*Kensey* has been discussed in detail in the preceding section. *Greenhalgh* instead teaches a bag for use in the

intravascular treatment of saccular aneurisms. This bag is formed from a plurality of flexible, resilient filamentary members braided into a tubular sleeve, and includes an opening for receiving a clotting medium, such as a platinum wire, on which blood clots can be formed by mechanical or electrolytic means.

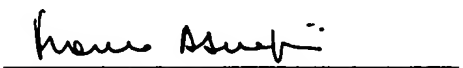
Contrary to the Examiner's contention, *Kensey* fails to provide all the elements of Applicant's invention except for the use of a platinum wire as a blood congealing agent, because, as proven above, *Kensey* teaches neither a device for extruding an autologous plug into a puncture tract, nor the controlled mixing of the patient's blood with a congealing agent inside the device. Therefore, the addition of the platinum wire as taught by *Greenhalgh* does not correct the deficiencies in *Kensey*.

At least for these reasons, the withdrawal of the rejection of claims 34-35 under 35 U.S.C. 103(a) is respectfully requested.

Conclusion

In view of the foregoing remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims.

Dated: December 5, 2006 Respectfully submitted,



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